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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,572	04/28/2006	Ushio Iwamoto	P28765	8899
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EXAMINER				
UNDERDAHL, THANE E				
ART UNIT		PAPER NUMBER		
1651				
NOTIFICATION DATE		DELIVERY MODE		
06/25/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/559,572

Applicant(s)

IWAMOTO ET AL.

Examiner

THANE UNDERDAHL

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 2/14/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-138 is/are pending in the application.
- 4a) Of the above claim(s) 91-104 and 121-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 105-120 and 137, 138 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is in response to the Applicant's reply received 2/14/08. Claims 91-138 are pending. Claims 91-104 and 121-136 are withdrawn. Claims 1-90 are cancelled. Claims 105-120 have been amended. Claims 137 and 138 are new.

RESPONSE RESTRICTION REQUIREMENT

The Examiner acknowledges that the Office summary mailed did not enter the pending and withdrawn claims correctly. This has been corrected in the above summary.

The Applicant contends on page 13 of their response "that the support for the lack of unity of invention is not appropriate because the Office Action has not established that any claimed subject matter is rendered non-patentable over U.S. Patent No. 5,510,102" and that the Examiner "does not indicate how such subject matter renders the subject matter recited in claim 91 unpatentable". The Applicant directly contends that the U.S. Patent #5,510,102 does not disclose a porous polymer. However the previous Office Action (mailed 11/14/07) states on page 2, paragraph 2 that "U.S. Patent # 5510102 teaches an wound healing composition that is made of plasma, platelets and a porous polymer such as alginate that can form a gel that covers the wound like a sheet (see summary of invention and col 8, lines 64-67)." [emphasis added]. Alginate gels are well known in the art to be porous polymers as supported by two elementary references written or edited by Severian Dumitriu (Polymeric Biomaterials 2nd edition, 2002, see col 1 page 13, and Polysaccharides in Medicinal Applications, 1996, see Figures 91, 92 and page 199, 1st line of body text). Indeed in light of the references One of ordinary skill in the art would recognize that alginate gels are inherently porous and as such U.S. Patent # 5510102 does teach the composition of claim 91 and thus unity is lacking in those claims. Therefore the restriction requirement will remain and a complete action on all pending claims will not be forthcoming.

Response to Applicant's Arguments— 35 U.S.C § 112

In the response submitted by the Applicant the 35 U.S.C § 112 rejection of claims 105-120 is withdrawn in light of the Applicant's amendments or direction pointed to in the specification. However when considering the definition of "Mature Cell", the Examiner notes that there was not a concrete definition, only examples of mature and immature cells. In this case the Examiner will take a broadest reasonable definition of

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"Mature Cell" in the art which is a fully differentiated cell that has reach its full natural growth and development which is opposite of an immature cell such as a stem cell or precursor cell as supported by Answers.com (Definition 1a).

Response to Applicant's Arguments— 35 U.S.C § 102

In the response submitted by the Applicant, the 35 U.S.C § 102 (b) rejection of claims 105, 106, 107, 115 and 120 over Slepian et al. (U.S. Patent # 5843156) were considered but not found persuasive even with the current amendments. The Applicant argues that the composition of Slepian et al. is applied to the body in a fluent state and so does not anticipate the limitations that "contacting at least one of leukocytes and platelets with a sheet-shaped porous body to trap...leukocytes and platelets on the" surface of the sheet-shape (Applicant's Response page 17, last 2 paragraphs).

However the Examiner does not agree when Slepian et al. is viewed in full especially when considering Figure 1, steps 1-8 and its description on column 12, lines 1-37. Indeed the porous gel is applied in a fluid state in step 7 to the inner lumen of a blood vessel. However the gel cures into a sheet-shaped porous body in step 8. Once the gel is cured blood flow is restored. So inherently the porous sheet has contact with blood which inherently contains a suspension of leukocytes and platelets. Also Slepian et al. teach this sheet contains attachment peptides such as selectins and Sialyl Le^x that can specifically bind leukocytes ("white cells") and platelets (col 14 lines 35-40). Therefore since Slepian et al. teach a sheet that is exposed to blood (which is by definition a cell suspension that contains leukocytes and platelets) and this sheet has

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the means to bind or trap leukocytes and platelets via the attachment peptides on its surface, the limitations of claims 105, 106, 107, 115 and 120 remain anticipated. Also since the indefiniteness of claims 112-114 have been clarified by defining the antecedent basis of the "cell suspension" with claim 105, these claims are anticipated as well. This is because the sheet is exposed to the autologous blood of the subject. The blood of the subject is inherently a fresh (less than 48 hours after sampling) cell suspension of mature leukocytes and platelets and has contact with the sheet which has binding agents to trap these cells.

Therefore the rejection stands and is repeated below with modifications to address the claim amendments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 105, 106, 107, 115 and 120 as well as amended claims 112-114 remain rejected under 35 U.S.C. 102(b) as being anticipated by Slepian et al. (U.S. Patent # 5843156).

These claims are drawn to a method to prepare a wound-healing material. That comprises a step of trapping at least leukocytes or platelets obtained from contacting a fresh cell suspension of autologous blood still circulating in the body and in

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a porous sheet with a thickness of 0.01 mm to 3 mm. The material can be a porous material with pore diameter of 1.0 to 40 μm .

Slepian et al. teach a polymeric sheet material that contains entrapped platelets and mature leukocytes from autologous blood that were bound by attachment peptides such as selectins and Sialyl Le^x (col 14, lines 35-40). This sheet covers the wound to form a porous layer (col 11, lines 28-40). The sheet is 0.001 to 1.0 mm in thickness (col 11, line 33). Slepian et al. further teaches this material has pores with 30 to 40 μm in diameter (col 11, lines 30-35).

Therefore the reference anticipates claims 105, 106, 107, 115 and 120 as well as amended claims 112-114.

Response to Applicant's Arguments— 35 U.S.C § 103

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) rejection of claims 105-115 and 120 over Slepian et al. (U.S. Patent # 5843156) as well claims 105-115, and 117-120 over Slepian et al. in view of Hood and claims 105-120 over Slepian et al. and Hood in further view of van Blitterswijk et al. (U.S. Patent # 6383220) were considered but not found persuasive.

Concerning the remaining 35 U.S.C § 103 (a) rejections in the Office Action the Applicant argues that since the amendments include a step that the leukocytes and platelets are contacted or filtered with the cell suspension overcome the teachings of Slepian et al. that they in turn overcome the remaining rejections that use these references. However as detailed above the Examiner disagrees and believes that the application of Slepian et al. is proper. The Applicant generally states that one of ordinary skill in the art would not have been motivated to modify the invention of Slepian

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et al. However, the Applicant did not provide additional arguments specifically pointing out the errors in motivation of combining and modifying Slepian et al. with the additional references of Hood and van Blitterswijk (Applicant's Response, page 18 paragraph 3 and 4). The Applicant simply points out that the deficiencies listed in the 102 (b) over Slepian et al. are not cured by the additional references (Applicant's Response, page 18 paragraph 4). However the deficiencies listed in the Applicant's response are addressed by Slepian et al. so therefore the rejections remain.

Furthermore in view of the entire reference Slepian et al. do indeed teach that their cured porous sheet is a filter. Slepian et al. teach that their cured sheet has selective permeability to gasses to specific cell sizes (Slepian, col 7, line 55 to col 8 line 6). Therefore the rejections stand and are repeated below with modifications to address the amended claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 105-115 and 120 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian et al. (U.S. Patent # 5843156) as applied to claims 105, 106, 107, 115 and 120 above and for the following rational.

Slepian et al. does teach a porous material that can entrap platelets and other cells (col 8, lines 45-50) such as leukocytes (col 14, lines 35-40) from autologous blood

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and the pores are 30 to 40 μm in diameter (col 11, lines 30-35). What Slepian et al. does not teach is that the sheet preferentially entraps platelets and leukocytes to erythrocytes. However Slepian et al. does teach that pore size can be adjusted to exclude large cells (col 11, lines 30-35) such as erythrocytes to "satisfy a wide variety of biological or clinical situations" (col 11, lines 39 and 40). Therefore it would have been obvious to someone skilled in the art to modify the material to have pores large enough to exclude large cells but incorporate platelets.

Furthermore while claims 109 to 114 limit the origin of the platelets such as the time acquired and the source. However, it would have been obvious to someone skilled in the art to obtain the platelets from these or other sources since it is well known in the art that platelets can be collected at various times and from various sources such as autologous blood or allogeneic blood since these would serve the same purpose in the method (M.P.E.P. § 2144.06). It would also be obvious to use allogeneic blood from an extracorporeal source in the surgical settings (col 1, lines 55-65) in particular vascular surgeries (col 22, lines 60-65) such as those Slepian where blood transfusions are commonplace and at times necessary in surgery.

Therefore the references listed above renders obvious claims 105-115 and 120.

Claims 105-115, 117-120 and 137, 138 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian et al. as applied to claims 105-115 and 120 above, and further in view of Hood (U.S. Patent # 5733545).

The description and rejection of claims 105-115 and 120 are listed in the 35 U.S.C § 103(a) rejection above. Claims 117-119 adds the step of incorporating fibrins into the wound healing material and washing the material. This process is carried out in a openable liquid-tight container.

While Slepian et al. do teach that fibrin can be included in their material (Slepian col 14, lines 44-48). However Slepian et al. do not teach that the method step includes filtration followed by concentration. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Hood. Like Slepian et al., Hood teach a wound sealant composition made from platelets and at least leukocytes (Hood, see Abstract). Hood also teach a wound sealant composition that contains fibrin that is made by filtering the composition into a flexible sheet (Hood, col 6, lines 20-25). Therefore it would have been obvious to combine the teachings of Slepian et al. and Hood since both teach a similar methods for the purpose of wound healing. Since both methods are known in the art it would be obvious to combine already known methods that achieve the same result it would be obvious to combine those methods to achieve the same predicted result, which in this case is the creating of a wound sealant composition (KSR International Co. v. Teleflex Inc.).

Furthermore while claims 118 and 119 add the steps of washing the wound healing material which is not explicitly taught in either of the above references this would be obvious to one of ordinary skill in the art. Since washing and sterilizing any material before it is applied to an open wound is soundly obvious in the art. In, common wound sealing methods, such as the application of bandages, one of ordinary skill in the

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art would rightly assume that the commercially available bandages were washed and sterilized in the factory before they were applied. The limitation in claim 119 that the washing be done in a water tight container with an inlet and outlet is also obvious to one of ordinary skill in the art since washing commonly involves water and agitation. One of ordinary skill in the art would recognize that agitating water in a container that is not liquid tight is would lead to an unnecessary mess. Furthermore it would have been obvious to someone skilled in the art to use a container with a liquid inlet and outlet so as to easily introduce and expel the water during the washing process, similar to the method used by a typical household washing machine.

Therefore the references listed above renders obvious claims 105-115, 117-120 and 137, 138.

Claims 105-120, 137 and 138 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian et al. and Hood as applied to claims 105-115, 117-120, 137 and 138 above, and further in view of van Blitterswijk et al. (U.S. Patent # 6383220).

The description and rejection of claims 105-115 and 117-120 are listed in the 35 U.S.C § 103(a) rejection above. Claim 116 incorporates fibroblasts into a wound healing material.

While Slepian and Hood et al. teach a material that is for wound healing and contains platelets as well as fibroblast growth factors (Slepian, col 8, lines 5-10). They do not teach the incorporation of fibroblasts into the sheet-like body. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in

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view of the teachings of van Blitterswijk et al. He teach the a wound-healing composition that incorporates fibroblasts (van Blitterswijk, col 4 lines 1-5 and 37-40). It would have been obvious to someone skilled in the art to add fibroblasts to wound healing method taught by Slepian and Hood. Slepian et al. provides motivation by include a fibroblast growth factor to promote the accumulation and incorporation of fibroblasts into the wound to expedite healing. The reasonable expectation of success is provided by van Blitterswijk et al. who teach that indeed, fibroblasts can be incorporated into the material to expedite wound healing. Therefore the references listed above renders obvious claims 105-120, 137 and 138.

In summary no claims, as written, are allowed for this application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

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/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651

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